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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/643,319

08/19/2003

Michael D. Ruff

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09/10/2008

WOMBLE CARLYLE SANDRIDGE & RICE, PLLC

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P.O. BOX 7037

ATLANTA, GA 30357-0037

EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/643,319	<b>Applicant(s)</b> RUFF ET AL.	
	<b>Examiner</b> ERIC E. SILVERMAN	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 43-46, 49-53 and 55-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-46, 49-53 and 55-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8-13-08, 7-15-08</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/15/2008 has been entered.

Claims 43-46, 49-53 and 55-57 are pending in this action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43-46, 49-53, and 55-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 43 recites "dibasic calcium phosphate dehydrate". This is believed to be a typographical error; it is believed that Applicants' intended "dibasic calcium phosphate dihydrate." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

Claims 43-46, 49-53, and 55 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,958,458 to Norling in view of US 5,788,987 to Busetti for reasons of record and those discussed below.

Claims 56 and 57 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Norling in view of Buseti as applied to claims 43-46, 49-53 and 55, and in further view of US 2003/0050228 to Ekwuribe.

### ***Response to Arguments***

Applicants' arguments have been fully considered, but are not persuasive.

Applicants' argue that the art does not teach or suggest the use of a core that is exclusively dibasic calcium phosphate dihydrate. Specifically, Applicants' allege that both Norling and Buseti teach the use of active ingredients in the core, or the use of more than one core ingredient. In response, Norling at claim 1 teaches a core comprising a pharmaceutically acceptable inert carrier which may be calcium phosphate. In this claim, the active drug is "present in a layer in the outer surface of the cores." This clearly suggests that there is no active agent in the core, and that the core may be made out of inert carrier alone (calcium phosphate being one such carrier). Buseti shows the utility of one species of calcium phosphate, dibasic calcium phosphate dihydrate, as a core in an insulin delivery system. It is noted that, while Norling may also teach the combination of actives with the inert core, such additional teachings do not detract from the suggestion at claim 1 to use a core having only an inert material. From Buseti, the artisan would expect the species of dibasic calcium phosphate dehydrate to be especially effective. Thus, when all of the teachings of the prior art references are taken together, the idea of using a single-component inert bead "core" coated by an active is known, as is the idea of using a dibasic calcium phosphate dehydrate as the inert component of a core bead for insulin delivery. It therefore follows

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that the claims represent prima facie obvious subject matter. Applicants' have not separately argued the rejection of claim 56 and 57, and as such, it is understood that Applicants' believe these claims to be patentable only insofar as their parent claims are also patentable; no parent claims are patentable at this time.

### ***Conclusion***

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/  
Examiner, Art Unit 1618